

State of the State of Drug Compounding in Minnesota

There continues to be much concern and confusion in the veterinary profession regarding what **is** and **isn't legal** for veterinarians to do with compounded drugs for our patients. Compounded drugs and compounding pharmacies are under greater scrutiny at both state and federal levels following the recent events of the contaminated compounded injectable steroids in humans. The FDA and the State Boards of Pharmacy have jurisdiction over drug compounding, drug manufacturing and compounding pharmacies. Caught in the middle of this dilemma is the veterinarian who is trying to provide the best veterinary care possible and keep the best interest of their patient in mind. The following questions have been presented to the Minnesota Board of Veterinary Medicine along with the answers given.

1. **Can I still prescribe compounded drugs for my patients?** The answer is yes, **BUT.....**
You can prescribe compounded drugs for your patient. If the drugs are compounded by a pharmacy, the prescription for the drug must be patient specific and can only be used for the treatment of the animal the medication was prescribed for. In addition, the pharmacy that is compounding the drug(s) must be licensed by the Minnesota Board of Pharmacy. If the pharmacy is not located within Minnesota, the pharmacy must be licensed by the Minnesota Board of Pharmacy as a non-resident pharmacy. No pharmacy can dispense drugs, compounded or otherwise, to the patient or end user in Minnesota unless the pharmacy is licensed by the Minnesota Board of Pharmacy.
2. **So how does my patient / animal owner get these compounded drugs?** The compounding pharmacy can send or deliver the prescribed drugs to the animal owner or to the prescribers (veterinarians) office. The animal owner can pay the pharmacy directly or the animal owner can pay the veterinarian for the **cost** of the compounded drug. Minnesota Board of Pharmacy Rule prohibits the practitioner from adding a "mark-up" to the drugs. The only allowable additional cost that the practitioner can add to the compounded drugs is limited to incidences when the practitioner must educate or demonstrate to the animal owner specific handling instructions, hazards or administration instructions. This additional cost is usually a one-time event if the compounded drug is prescribed multiple times.
3. **Can I get compounded drugs from a compounding pharmacy and keep them at my clinic to be prescribed and dispensed to my patients as the need arises?**
Unfortunately, the answer is no with very few exceptions. Compounded drugs must be prescribed, compounded and dispensed on a patient specific basis. The law and Rule does not allow for obtaining compounded drugs prescribed to the "clinic cat" that will later be prescribed and dispensed to other patients. "Bulk" compounded drugs from a

compounding pharmacy that is intended to be used by a veterinarian as 'shelf stock' and dispensed to patients may only be obtained from a compounding pharmacy that is licensed by the Minnesota Board of Pharmacy as a **DRUG MANUFACTURER** and is also a **LICENSED WHOLESALER** by the Minnesota Board of Pharmacy. Some compounding pharmacies imply that they can provide the practitioner with bulk compounded drugs for "office use" and can be dispensed to patients, but very few compounding pharmacies meet the legal requirements as a licensed drug manufacturer and licensed wholesaler. To verify if a pharmacy is licensed by the Minnesota Board of Pharmacy or if it is a licensed drug manufacturer or licensed wholesaler, you can check it out at the Minnesota Board of Pharmacy website at <https://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx>.

4. **So what am I supposed to do if I need to prescribe compounded drugs to my patients and I can't get bulk compounded drugs from a compounding pharmacy?** A legal, but not necessarily the optimal solution, is for the veterinarian to compound the drugs and medications themselves (MN Statute §156.18 subdivision 1,e). A practitioner (veterinarian) can legally compound drugs and medications that can be prescribed and dispensed to their patients. In fact, a practitioner can "bulk" compound a reasonable amount of compounded drugs and medications and keep as shelf stock to prescribe and dispense to their patients as the need should arise. Practitioners that chose to compound drugs and medications should follow drug compounding best practices and observe reasonable expiration dates and shelf life. Anytime that a practitioner prescribes or dispenses a compounded drug or medication for animal use, it is important that the veterinarian inform the animal owner that the drug is not a FDA approved drug formulation but the medication has been prepared in a way that better addresses medication dosage and ease of medication administration and client compliance.

Legislation passed in the 2013 legislative session will allow the Minnesota Board of Pharmacy to develop Rules that the Pharmacy Board hopes will address the problems that veterinary practitioners are facing with the compounding pharmacy / drug / medications. Although these Rules will not be developed overnight, there is promise that the compounding drug dilemma may improve and better reflect the way that veterinarians use compounded drugs. Stay tuned.